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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/375,609 08/17/99 RHEINS

L 09373/002001

020985
FISH & RICHARDSON, PC
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO CA 92122

HM22/0712

EXAMINER

PRASAD, S

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

07/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.		Applicant(s)	
	09/375,609		Rheins et al.	
	Examiner		Art Unit	
	Sarada C Prasad		1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-136 is/are pending in the application.
- 4a) Of the above claim(s) 11-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-136 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

Detailed Action

1. Receipt of Applicants' arguments and amendments filed in Paper No. 9 (5/3/01) is acknowledged. Amendments to claims 82, 97 and new claims 104-136 have been entered. Currently, claims 64-136 are under consideration by the examiner.
2. The following previous rejections and objections are withdrawn in light of Applicants' amendments filed in Paper No. 9 (5/3/01).
 - (i) Objections to claims 97 and 103;
 - (ii) the rejection of claims 66-69 under 35 U.S.C. 112, first paragraph-scope (3b) based on the use of phrase 'skin sample';
 - (iii) the rejection of claim 82 under 35 U.S.C. 112, second paragraph- based on acronym descriptions;
3. Applicant's arguments filed in Paper No. 9 (5/3/01), have been fully considered but were deemed persuasive in part. The issues remaining and new issues, are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 first paragraph-scope

5. Claims 64-103 are rejected under 35 USC § 112 first paragraph in Paper No.7 (1/31/01)

This rejection of record is being maintained for reasons of record set forth in pages of the previous office action (Paper No.7, 1/31/01). This rejection now applies to original claims 64-103, and new claims 104-136.

Art Unit: 1646

5a. 35 USC §112 first paragraph:

For the rejection based on the scope of enablement due to recitation of '...detecting a nucleic acid..' in Paper No.7 (1/31/01), the Applicants assert that 'the specification provides ample support for detecting nucleic acid in a skin sample (see page 9, line 10-page 13, line 4). The rejection is based on the scope and enablement in terms of the utility of detecting and quantitating all nucleic acids (Paper No. 7, page 3, 3rd para-entire) in the various skin cells, other than that of cytokines listed as IL-4, IL-8, IL-13, iNOS, IFN- γ during allergic contact dermatitis/irritant contact dermatitis type reactions (ACD/ICD) with GAPDH as a control in each case. The Applicant's response addresses this rejection as if it were meant for lack of enablement for detecting the levels of all nucleic acids of all cytokines. The Examiner has stated that the detection and quantitation of all nucleic acids in the skin cells is neither supported by the disclosure nor seems necessary. Based on reference levels provided in the working examples, amount of guidance provided, the extent of correlation obtained, expected levels of cytokines other than IL-4, IL-8, IL-13, iNOS, IFN- γ are not known to distinguish ICD from ACD.

Therefore, the rejection of record based on the broad recitation of 'detecting a nucleic acid in a skin sample...' in claims 64, 104, 135 and 136 is being maintained. Claims 65-94, 104-134 are rejected insofar as they depend on claims 64, and 104.

5b. 35 USC § 112 first paragraph:

The Applicants tried to address this rejection based on the scope of enablement due to recitation of '..skin cell samples' by addition of new claims 104-115 describing the details of collection of each layer of skin containing one cell type with each tape stripping. Applicants'

arguments are fully considered, however were only persuasive in part. Neither the disclosure, nor examples, nor the response to earlier office action addressed the question of how many applications of tape stripping of the skin can be tolerated by the subject without being invasive. Instant disclosure describes stripping can be done up to a maximum of 25 times (page 18, 1st para, lines 3-4). Considering the fact that the fewer the tape strippings the better it is for the non-invasive character of the instantly claimed method of sample collection, it is not specified in the examples as to how many strippings, suggestive of more than 1, more than 15, more than 20, up to the intended maximum of 25, an individual could tolerate. The new claims 104-115 were crafted to address the enablement rejection of Paper No. 7(1/31/01), even though such suggestion was there in the specification earlier. However, due to lack of guidance of how repeated tape stripping is tolerated while also yielding consistent layers of skin cell samples, with a correlation to consistent levels of cytokines measured, this rejection of record is being maintained and it now applies to claims 66-69, 104-115.

Claim Rejections - 35 USC § 102

6. Claims 64-65, 70-82, 85-91, 95-101 are rejected under 35 U.S.C. 102 (b) as being anticipated by Nickloff and Naidu (1994).

This rejection of record is being maintained for reasons of record set forth in the earlier office action. This rejection now applies to claims 64-65, 70-82, 85-91, 95-101 and new claims 104-136.

Applicants assert that non-invasiveness of the method of instant skin cell sample collection is what distinguishes the prior art of Nickloff and Naidu (1994) from the instant claims. Support for that same assertion is not clear from the specification because neither the

Art Unit: 1646

disclosure nor examples nor the response to earlier office action (Paper No. 8, 5/3/01) addressed the question of how many applications of tape stripping of the skin can be tolerated by the subject without being invasive. Therefore, this rejection of record is being maintained.

Claim Rejections - 35 USC § 103

7. Claims 64-65, 70-74, 76-82, 85-91, 93, 96-101, 103 under 35 U.S.C. 103 (a) as being obvious over Molen et al. in view of Kondo et al. This rejection of record is being maintained and it now applies to claims 64-65, 70-74, 76-82, 85-91, 93, 96-101, 103, 104-115.

Applicants assert that teachings of Kondo et al. and Molen et al. together are not completely equivalent to or do not teach all aspects of the instant invention. These two citations together teach what would have been prima facie obvious to one of skill in the art, at the time the invention was made, to use tape stripping for skin sample collection, and to determine the levels of cytokines in the skin cells in the determination of the type of dermatitis. The use of combined teachings of Kondo et al. and Molen et al., in the instant case, would satisfy the requirement of the obviousness type 103(a) in the instant case. However, if each of the citations individually were to teach the instant invention completely, it would have been a 102(b) type rejection.

Conclusion.

8. No claims are allowed.

Art Unit: 1646

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
July 8, 2001

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER